AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Withdrawn) A method for the preparation of an osteoinductive agent including the steps of modifying a naturally occurring biocompatible biopolymer by subjecting the biopolymer in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas and annealing the resulting product in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form; thereafter removing any residual mediating gas; and disposing the product in a hermetically sealed container containing oxygen-free gas.

2. (Withdrawn) A method according to claim 1 wherein the naturally occurring biocompatible biopolymer is selected from the group consisting of collagen; hyaloronic acid; demineralised bone (DMB); and mixtures thereof.

3. (Withdrawn) A method according to claim 2 wherein, in the case of the said mixture, the method includes the steps of first subjecting the biocompatible biopolymers to the said source of ionising radiation in the presence of the said mediating gas separately from each other; and thereafter mixing the irradiated biocompatible biopolymers.

4. (Withdrawn) A method according to claim 2 wherein, in the case of the said mixtures, the method includes the steps of first mixing the biocompatible biopolymers; and thereafter subjecting the mixture to the said source of ionising radiation in the presence of the said mediating gas.

5. (Withdrawn) A method according to claim 3 wherein the biocompatible biopolymers are subjected to a minimum absorbed irradiation dose of16 kGy.

6. (Withdrawn) A method according to claim 1 wherein the hermetically sealed container is a secondary container and wherein the method includes the further step of disposing the product inside a first primary container, which is disposed inside the hermetically sealed secondary container.

7. (Withdrawn) A method according to claim 6 including the further step of providing the first primary container in the form of a syringe-type container, having a plunger for dispensing the contents thereof, and an outlet opening having a diameter larger than 0.6 mm, to allow for the dispensing of the said product in a relatively viscous form.

8. (Withdrawn) A method according to claim 6 including the further step of filling the space in the first primary container not occupied by the product with the said oxygen-free gas.

9. (Withdrawn) A method according to claim 6 which includes the further steps of providing a second primary container; disposing liquid in the second primary container; and disposing the second primary container inside the hermetically sealed secondary container.

10. (Withdrawn) A method according to claim 9 including the further step of providing the said liquid in the form of pyrogen-free water.

11. (Withdrawn) A method according to claim 9 which includes the further step of disposing the hermetically sealed secondary container inside a hermetically sealed tertiary container.

12. (Withdrawn) A method according to claim 11 including the further step of filling the tertiary container with oxygen-free gas and capturing the oxygen-free gas inside the hermetically sealed tertiary container.

13. (Withdrawn) A method according to claim 11 wherein the steps of providing the secondary and tertiary containers include the step of vacuum forming these containers from a radiation stabilised, gas-impermeable material.

14. (Withdrawn) A method according to claim 9 including the further steps of subjecting the said containers and their contents, in kit form, to a terminal radiation sterilisation process.

15. (Withdrawn) A method according to claim 14 wherein the sterilisation process includes the step of subjecting the containers and their contents to a minimum absorbed irradiation dose of 25 kGy.

16. (Withdrawn) A method according to claim 14 which includes the further step of opening the sealed containers and mixing the said sterile liquid with the said product in a dry particulate form to hydrate the product to form an osteoinductive agent in the form of a pliable viscous putty.

17. (Withdrawn) A method according to claim 16 which includes the further step of dispensing the osteoinductive agent from the first primary container to a bone reconstruction site.

18. (Withdrawn) A method according to claim 1 including the step of providing the oxygen-free gas in an inert form.

19. (Withdrawn) A method according to claim 18 including the further step of providing the said gas in the form of nitrogen.

20. (Withdrawn) A method according to claim 1 wherein the said mediating gas is selected from the group consisting of acetylene, ethylene and propylene.

21. (Currently Amended) A kit for preparing and dispensing an osteoinductive agent product including a plurality of modified naturally occurring biocompatible biopolymers, the biocompatible biopolymers being selected from the group consisting of collagen, hyaloronic acid, and demineralised bone (DMB), which are first mixed and thereafter ~~was~~ subjected, in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas, the mediating gas being selected from the group consisting of acetylene, ethylene and propylene, and annealed in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form, the product being disposed in a hermetically sealed container containing oxygen-free gas and radiated again to ensure that the product is sterile.

22.-24. (Cancelled)

25. (Currently Amended) A kit according to claim ~~23~~ 21 wherein the biocompatible biopolymers are subjected to a minimum absorbed irradiation dose of 16 kGy.

26. (Previously Presented) A kit according to claim 21 wherein the sealed container is a secondary container and wherein the product is disposed inside a first primary container, which is disposed inside the sealed secondary container.

27. (Original) A kit according to claim 26 wherein the first primary container is in the form of a syringe - type container, having a plunger for dispensing the contents thereof and an outlet opening having a diameter larger than 0.6 mm, to allow for the dispensing of the product in a relatively viscous form.

28. (Previously Presented) A kit according to claim 26 wherein the space in the primary container not occupied by the product is filled with the said oxygen-free gas.

29. (Previously Presented) A kit according to claim 26 which includes a second primary container containing a liquid and being disposed inside the hermetically sealed secondary container.

30. (Previously Presented) A kit according to claim 29 wherein the liquid is in the form of pyrogen-free water.

31. (Previously Presented) A kit according to claim 29 wherein the hermetically sealed secondary container is disposed inside a hermetically sealed tertiary container.

32. (Original) A kit according to claim 31 wherein the tertiary container is filled with oxygen-free gas.

33. (Original) A kit according to claim 32 wherein the secondary and tertiary containers are vacuum formed from a radiation stable, gas - impermeable material.

34. (Previously Presented) A kit according to claim 29 wherein the said containers are subjected, in kit form, to a terminal radiation sterilisation process.

35. (Previously Presented) A kit according to claim 21 wherein the oxygen-free gas is inert.

36. (Original) A kit according to claim 35 wherein the gas is nitrogen.

37. (Cancelled)

38. (Withdrawn) A method of reconstructive bone surgery in humans or animals including the steps of providing the kit in according to claim 34; opening the secondary and tertiary containers; hydrating the dry particulate product by injecting the sterile liquid into the first primary container and mixing the liquid and the product to form a putty; dispensing the putty into a bone reconstruction site; and closing the site to allow bone reconstruction to take place.

39. – 41. (Cancelled)